



QUESTIONS AND ANSWERS

Request for Proposal (RFP): Tuberculosis Biomarkers Landscape including the Prioritisation of Biomarkers for Further Development

#	Supplier Question	Wellcome response
1	How is the governance and funding organised in cases of interinstitutional teams such as ours?	One lead institution should hold the contract with Wellcome and one named investigator at the lead institution should be responsible for overall project management and delivery of the work. The institutions involved should establish a project management and governance framework between themselves to enable effective team working and reimbursement of different contributing institutions as appropriate. Suppliers should include in the budget any project management and administrative support required to enable effective governance and delivery of the project.
2	Is any practical exercise of biomarker validation expected during the project (e.g. using biobank data)?	This is not an expected core component of the proposal. If teams consider it is feasible to achieve this within the project timescale, it can be included in the proposal.
3	While the review's objective is to identify the barriers and enablers of TB biomarker development, as well as candidates for further clinical development, will the output also be feeding into any other objective or project?	We expect the outputs of this review to guide Wellcome's thinking and work in this space, and to be useful to the wider TB biomarkers field.
4	What are the main considerations being asked for when asking about the stage of development of each biomarker assay (objective 1)?	We would like the supplier to summarise the pipeline of potential biomarker assays and the progress that has been made to bring each from early-stage laboratory development towards eventual clinical use.



5	<p>Whether the Wellcome trust provides any support in bringing together the stakeholders (identified by us) especially the industry experts for consultation meetings during the project?</p>	<p>For the stakeholder consultation meeting at Union TB 2024, because of the short timescale between the contract start date and the Union TB conference, Wellcome will book an appropriate meeting room and any catering needed, in the vicinity of the conference venue. The supplier will be responsible for planning the meeting, inviting relevant stakeholders and running the meeting.</p> <p>For the second stakeholder consultation in spring 2025, the supplier should plan to make all meeting arrangements. If the supplier needs to request any logistical support from Wellcome, this can be discussed at the contract stage.</p> <p>Please include all costs associated with arranging the stakeholder meetings in the proposal budget; this can include but is not limited to venue hire (spring 2025 only), catering and AV costs, travel costs, administrative support for meeting organisation and any honorarium payments for participants</p>
6	<p>Has Wellcome already interacted with the Union TB Conference organizers, regarding space for the side meeting? Or is this meeting occurring outside of the conference programme/logistics?</p>	<p>This meeting will occur outside of the conference programme.</p>
7	<p>Could you please confirm if Wellcome Trust representatives will attend the consultation meetings and if so, how many would attend (this is solely for the purpose of providing accurate costings for the meetings)?</p>	<p>Please plan for four Wellcome Trust representatives to attend each meeting.</p>
8	<p>What type of people (sector, profiles) would you expect to join the side meeting at Union TB and how many?</p>	<p>We suggest a meeting of up to 30 participants would enable everyone present to contribute. Participants should include (but are not limited to) researchers involved in TB biomarker research, researchers and health policymakers currently involved in delivery of TB treatment in lower resourced settings and industry representatives. The</p>



		supplier should consider how patient perspectives can best be incorporated into the biomarkers prioritization exercise.
9	With the convening of a stakeholder meeting at the Union Conference – How broad a range of attendees at the meeting would be allowed? Would we have access to the list of attendees to the Union conference so we can invite them to the meeting or would we be required to ensure all identified stakeholders attend the meeting? Would we need to include travel costs for stakeholders to the event?	<p>Please see question 8 for stakeholders who must be included, we welcome supplier suggestions of additional attendees. We expect you to leverage your own networks and expertise in identifying and engaging relevant stakeholders including participants of the Union TB meeting.</p> <p>There will not be access to lists of Union conference attendees beyond what is publicly made available by the conference organisers.</p> <p>If the supplier identifies key stakeholders who are not attending the Union TB meeting, it will be possible to run a hybrid meeting and have a minority of attendees online. We do anticipate however that, given the size of the conference, it should be possible for representatives of the key groups of stakeholders to be mainly present in person.</p> <p>As we expect to invite in-person attendees who are already present at the conference, and to schedule the meeting during the conference so that travel arrangements do not have to be altered in order to attend, we do not anticipate needing to reimburse attendees' travel costs to the conference.</p> <p>Any additional travel costs of the supplier team, which would not have been incurred other than to carry out this contract, should be included in the budget.</p>
10	What level of interaction/involvement is expected from the Wellcome team in the development of the literature review – particularly from an editorial capacity?	The supplier is fully responsible for carrying out the literature review. At the point of contract award, Wellcome and the supplier will agree on a more detailed specification of the documents to be produced during the project and the timeline for their delivery. This will include building in time for Wellcome to review and approve documents such as meeting agendas, a draft structure for the review, and the final review document.



11	Could you please clarify if the Wellcome Trust will assign a contact person to discuss different aspects of the service and to optimize it?	Yes, there will be named contacts at Wellcome for both contract queries and delivery of the project.
12	Since the service contract is expected to start in October 2024 and the Union Conference will be held November 12-16, there is little time for organizing a side meeting. Could you please clarify if the organizers are aware of the planned satellite session?	The side meeting will not form part of the official Union Conference programme. We recognize the tight timeline and expect the successful applicant to begin planning for this meeting immediately upon contract award. Please outline your approach to organizing this meeting within the given timeframe in your proposal.
13	Are you able to initiate this project sooner (i.e. before October) to allow the vendor to advance the literature review prior to the November Union TB conference?	To allow a fair and thorough supplier selection process, including giving adequate notice of interviews over the summer holiday period, it is unlikely that we can accelerate the timeline of the contract award.
14	The anticipated contract start date is Oct 2024 but is there a preferred/anticipated contract end date (i.e. would project end as Dec 2025 be acceptable)?	We expect the report to be finalized in May 2025, followed by a presentation of the findings to Wellcome and other funders and selected representatives.
15	Are you able to provide any guidance on the budget ceiling/range for this work?	Wellcome will be guided by the supplier as to what is a reasonable budget for this activity as we do not want limit ambition or innovation.



16	Engaged and well-informed stakeholders can be identified at the meeting. Could they be included as collaborators and compensated for time spent on the activity after the project's initiation?	We expect the team who will deliver the project to be identified in the application. If you anticipate carrying out further consultations with experts during the development of the report, please cost any appropriate remuneration into the budget.
17	Should funding for open access publications be included in our costings, or would Wellcome provide this separately?	Please include all anticipated publication costs in the budget.
18	Can the cost component of the RFP response be detailed in USD?	Costs can be submitted in most currencies (USD/GBP/EURO/CHF etc.)
19	The deadline for submitting a satellite session deadline for the Union TB conference in Nov 2024 is Aug 1, 2024 (prior to the anticipated notification of contract award in Sep 2024). Does this mean that the stakeholder meeting would be convened as a standalone event and a separate side event? This may have cost and resource allocation implications.	Yes, the stakeholder meeting will be convened as a standalone side event. Please see question 5 for logistical details.



<p>20</p>	<p>What is the scope of biomarkers for this effort? The RfP references lab-based biomarkers – would other biomarker modalities be in scope?</p>	<p>While the primary focus is on lab-based biomarkers, other modalities (e.g., imaging biomarkers) can be included if they are relevant to the key objectives outlined in the RFP and as guided by stakeholder consultations.</p>
<p>21</p>	<p>Is Wellcome only interested in biomarkers in clinical/diagnostics development or those at earlier discovery stages as well?</p>	<p>We would like a complete overview of the range of biomarkers across the development pipeline and the stages of TB infection and disease spectrum they may be used for.</p>
<p>22</p>	<p>Our team are interested in providing innovation, in addition to addressing the core RFP objectives, as outlined above. These components are not included in the current estimate. Are Wellcome interested in providing additional funding to address these areas?</p>	<p>Please provide a short description for suggested additional components in the full application, but clearly distinguishing them from the core requirements and providing separate costings. Once a supplier has been selected, any proposed additions to the core specification will be discussed between Wellcome and the supplier.</p>
<p>23</p>	<p>From the biomarkers identified during the review a workshop with a focus on biomarker development would be beneficial. Obstacles to the production and marketing of new detection platforms are considerable. Effective implementation of biomarkers requires consideration</p>	<p>We are open to the inclusion of additional stakeholder consultations during the project. Please include the details of any additional consultations you would like to arrange (including participants, timing, purpose and budget) in your proposal.</p>



	<p>of the performance of the biomarkers assay as well as the biology of the biomarker, meaning there will be no one-size-fits-all solution when it comes to biomarker assay validation and deployment. Would the addition of a TB biomarker development barriers and challenges workshop, separate to the meeting, be acceptable?</p>	
24	<p>Do you envision using the side meeting at Union TB to prioritize biomarkers for the use cases and set criteria or do you envision this objectives (#2) being addressed later in the project through an additional consultation?</p>	<p>We anticipate that the Union TB meeting will consult stakeholders on:</p> <ul style="list-style-type: none">• The most promising biomarkers for the three use cases identified in the RFP (Patient Stratification, Disease Progression, Response to Treatment). This component can include the questions of both what biomarkers exist and which biomarkers attendees consider to be most promising for each use case.• Multiple potential use cases for TB biomarkers have been set out in existing TPPs, and we expect the discussion to include consideration of which of these use cases (amended/updated as appropriate) are the most critical to facilitate the development of TB biomarker assays into clinical use, to achieve the overall goal of reducing TB transmission. The consultation should determine the prioritization criteria to be used by the supplier to conduct a systematic post-meeting biomarker prioritization exercise.• Barriers and enablers of TB biomarker development (including challenges of translation into clinical practice). <p>We are open to other means of structuring the stakeholder consultation, please set out any alternative suggestions in your proposal.</p>



25	Who are Wellcome's current partners in this space? The RfP references 'other funders' as a key audience for the readout	Wellcome collaborates with various organizations in TB research, including other major funders like the Bill and Melinda Gates Foundation and Novo Nordisk Foundation. However, the landscape analysis should be conducted independently, considering the broader TB research community.
26	What format are the draft and final reports expected in? .doc, .ppt or other?	For the final report, two documents (a main report suitable for Wellcome to share, and an additional document with any information, including sensitive material, for Wellcome's internal use) and an associated powerpoint summarizing the main findings are likely to be required. This will be agreed with the supplier at the contracting stage.
27	Will the Wellcome Trust be amenable to the contracted team using the outputs for additional research and/or teaching?	Wellcome is committed to open access and knowledge sharing. Wellcome may agree for the contracted team to use the outputs for additional research or teaching, provided that Wellcome is appropriately credited and that such use does not compromise the confidentiality of any sensitive information or intellectual property rights.
28	Is the final presentation of findings to Wellcome and funders at the end of the contract expected to be a virtual meeting or in-person?	This can be agreed at a later stage between Wellcome and the supplier, taking into account the geographical feasibility of an in-person meeting.
29	Can further details be provided on the type of validation proposed for the report conclusions?	We would like the second stakeholder consultation meeting to confirm whether a wider group of relevant diverse stakeholders (including academic experts, industry representatives and policymakers) agree with the draft report's conclusions on the most promising biomarkers for further development, or at least take their feedback into account. The aim is to ensure that the conclusions are robust, comprehensive, and widely accepted within the field.
30	Could you confirm that the expected proposal format is .doc?	Proposals can be submitted as word.docx or PDF format.